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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,720	07/18/2005	David John Pritchard	ABL-011.5P US	6344

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EXAMINER

COOK, LISA V

ART UNIT	PAPER NUMBER
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1641

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04/25/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/539,720	Applicant(s) PRITCHARD, DAVID JOHN	
	Examiner LISA V. COOK	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) 57-70, 75, 77, 79-83, 88, and 90-91 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) See Continuation Sheet are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims pending in the application are 1-13,17,22,26-28,30,33-39,43,44,52,57-70,75,77,79-83,88,90 and 91.

Continuation of Disposition of Claims: Claims subject to restriction and/or election requirement are 1-13,17,22,26-28,30,33-39,43,44,52,57-70,75,77,79-83,88,90 and 91.

DETAILED ACTION

Election/Response

1. Applicant's election with traverse of Group I (claims 1-13, 17, 22, 26-28, 30, 33-39, 43-44, and 52) drawn to a method of measuring forms of Factor XIIa in a sample, in the reply filed on 2/4/08 is acknowledged. The traversal is on the following ground(s):

A. Examiner has arbitrarily required restriction between Group I & II. Applicant contends that the methods depend on claim 1 and Group II merely specifies that the sample is obtained from a subject having a disease or disorder. This argument was carefully considered and found persuasive the inventions of Groups I and II are rejoined.

B. Applicant contends that claimed inventions is a contribution over the prior art because the specification teaches that proteolysis cleavage of factor β XIIa can under go fragmentation to produce a 15kd construct that Applicant has termed Factor?XIIa (not known in the art). In addition Esnouf teaches isolation of non-activated Factor XIIa in vitro. This argument was carefully considered but not found persuasive. Esnouf et al. teach methods utilizing the same antibodies of the present invention (namely mAb 2/215). Accordingly the method taught by Esnouf et al. would detect the same Factor XIIa forms claimed and taught by the instant specification. The methods of detecting forms of Factor XIIa are not a contribution over the prior art and restriction is proper.

The requirement is still deemed proper and is therefore made **FINAL**.

2. Claims 70, 75, 77, 79-83, 88, and 90-91 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 2/4/08.

Amendment Entry

3. Claim 1 was modified. Claims 14-16, 18-21, 23-25, 29, 31-32, 40-42, 45-51, 53-56, 71-74, 76, 78, 84-87, 89, and 92-93 have been cancelled. *Please note claim 30 is dependent on canceled claim 29.* Currently claims 1-13, 17, 22, 26-28, 30, 33-39, 43-44, 52, and 57-69 have been rejoined and are under consideration. After reconsideration of the arguments and claims, the following species election is required.

Election/Restrictions

4. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

- A. Group I, claim(s) 1-13, 17, 22, 26-28, 30, 33-39, 43-44, and 52, are drawn to a method of measuring forms of factor XIIa, classified in class 435, subclass 7.1, for example. (A first method/process that measures/utilizes the special technical feature).

- B. Group II, claims 1 and 57-69, are directed to a method of measuring forms of factor XIIa in subjects with a disease or disorder, classified in class 424, subclass 146.1 and classified in class 435, subclass 13, for example. (A second method detecting/employing the special technical feature).

5. In addition to the species election above, If Applicant selects Group I for consideration one species from each of the following Groups must also be selected: *Please select one from C, D, and E for consideration.*

C. Group III – merely detecting or determining Factor XIIa forms without separation (claims 2, 26-28, and 33-39) *or* separation of Factor XIIa forms and then detecting or determining the separated forms (claims 3, 4, and 6-9).

D. Group IV – sample measured is body tissue (claim 10), sample measured is blood, plasma, cerebrospinal fluid, or serum (claims 10 and 11), *or* sample measured is urine, saliva, *or* tears (claims 10 and 12).

E. Group V – forms of Factor XIIa under investigation is cellular (claim 13), *or* forms of Factor XIIa under investigation is lipid bound (claim 17), *or* forms under investigation comprises complexes of two or more molecules of Factor XIIa (claims 22 and 52).

6. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

7. The claims are deemed to correspond to the species listed above in the following manner: Each of the species are independent and distinct requiring separate search and considerations. The following claim(s) are generic: 1, 5, and 43-44.

8. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: each species is directed to methods requiring independent and distinct reagent compositions, assay, formats, and/or sample types.

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9. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i)

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to LISA V. COOK whose telephone number is (571)272-0816. The examiner can normally be reached on Monday - Friday 7:30am to 3:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lisa V. Cook
Patent Examiner
Art Unit: 1641
Remsen 3C-70
571-272-0816
4/23/08

/Lisa V. Cook/
Primary Examiner, Art Unit 1641